The preamble of claim 4 properly sets forth a delivery apparatus. The delivery apparatus comprises an outer sheath, an inner shaft and a stent. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-4 and 6-13 were rejected as being unpatentable over U.S. Patent Number 5,324,304 to Rasmussen in view of U.S. Patent Number 6,136,006 to Johnson et al. (Johnson). This rejection is respectfully traversed.

Rasmussen discloses a catheter for delivering a self-expanding medical implant. The device comprises an internal filter catheter which is slidably arranged inside a standard guide sheath and is connected at its proximal end with an operating member which functions to push the filter catheter through the guide sheath. A tubular end member is connected to the distal end of the internal filter catheter slidably arranged inside the tubular end member, and is a filter retaining member with functions to releasably retain the anchoring legs of the filter element. The retaining element comprises slits in order to accommodate the bent hook at the free end of each leg.

Johnson discloses a device for delivering a self-expanding stent. The device comprises an elongated exterior catheter, an interior catheter which is positioned in the lumen of the exterior catheter and a stent. The exterior catheter comprises a hub, and the interior catheter comprises a hub. An annular sleeve detent region is formed between the hubs and a sleeve surrounds the interior catheter and abuts to the hubs to prevent any movement of the interior catheter axially relative to the exterior catheter.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck,* 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

The present invention, as claimed in amended independent claim 1, is directed to a delivery apparatus for a self-expanding stent. The apparatus comprises an outer sheath and an inner shaft located coaxially and slidably within the outer sheath. The inner shaft also comprises a stop releasably affixed on an exterior surface thereof. The stop is configured to allow the outer sheath to move a predetermined distance, thereby enabling partial deployment of a self-expanding stent.

The present invention, as claimed in amended independent claim 4, is directed to a delivery apparatus for a self-expanding stent. The apparatus comprises an outer sheath comprising an elongated tubular member, an inner shaft located coaxially within the outer sheath, and a substantially cylindrical self-expanding stent located within the outer sheath. The inner shaft includes a stop releasable affixed on an exterior surface thereof adjacent to

its proximal end. The stop is configured to allow the outer sheath to move a predetermined distance, thereby enabling partial deployment of a self-expanding stent. The inner shaft also including at least two grooves disposed thereon. The stent including at least two legs, each having a flange with one set in the grooves of the inner shaft.

Applicants respectfully submit that the cited prior art references, whether taken alone or in combination, fail to disclose or suggest all of the claim limitations. Rasmussen does not disclose or suggest a stop. Johnson discloses an annular sleeve detent that surrounds the proximal region of the interior catheter between two hubs. When positioned, the retaining sleeve surrounds the interior catheter and abuts the hubs to prevent any substantial movement of the interior catheter axially relative to the exterior catheter. Essentially, the sleeve functions as a safety detent preventing premature deployment of the stent. In the claimed invention, relative movement is allowed by the stop, thereby enabling partial deployment for proper positioning. Essentially, in the present invention, movement is designed into the apparatus, whereas in Johnson, no movement is permitted. Applicants also respectfully submit that there is simply no motivation or suggestion to modify the apparatus of Rasmussen based on the teachings of Johnson. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 5 was rejected as being unpatentable over Rasmussen in view of Johnson and further in view of U.S. Patent Number 6,221,096 to Aiba et al. (Aiba). This rejection is respectfully traversed.

Aiba fails to disclose or remotely suggest a stop as claimed in the present invention. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicants would be willing to interview the present case if the Examiner so desires.

The Amendment/Reply raises no new issues and places the application in form for allowance. Therefore, entry is proper and earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

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IN THE CLAIMS

Please amend the claims as follows:

1. (Twice Amended) A delivery apparatus for a self-expanding stent, said apparatus comprising:

a) an outer sheath, comprising an elongated tubular member having distal and proximal ends;

b) an inner shaft located coaxially and slidably within said outer sheath, said inner shaft having a distal end and a proximal end, said inner shaft having a [removable member] stop releasably affixed on an exterior surface thereof adjacent to its proximal end, said [removable member] stop being [sized such that it prevents said outer sheath from sliding along said inner shaft proximal to said removable member until it is removed therefrom] configured to allow said outer sheath to move a predetermined distance, thereby enabling partial deployment of a self-expanding stent, said inner shaft further including at least two grooves disposed thereon.

2. (Twice Amended) The apparatus according to claim 1 said [removable member] stop is semi-cylindrical and snap fits over said inner shaft.

3. (Twice Amended) The apparatus according to claim 2 wherein said [removable member]stop has an outside diameter larger than an inside diameter of said outer sheath.

4. (Twice Amended) A delivery apparatus for a self-expanding stent, said apparatus comprising:

a) an outer sheath, comprising an elongated tubular member having distal and proximal ends;

b) an inner shaft located coaxially within said outer sheath, said inner shaft having a distal end and a proximal end, said inner shaft having a [removable member]stop releasably affixed on an exterior surface thereof adjacent to its proximal end, said [removable member]stop being configured to allow said outer sheath to move a predetermined distance, thereby enabling partial deployment of a self-expanding stent [sized such that it prevents said outer sheath from sliding along said inner shaft proximal to said removable member until it is removed therefrom], said distal end of said inner shaft further including at least two grooves disposed thereon; and

c) a substantially cylindrical self-expanding stent located within said outer sheath, said self-expanding stent having a proximal end, a distal end, a longitudinal axis extending therebetween and an interior, said self-expanding stent further including at least two spaced apart longitudinal legs having distal and proximal ends, said distal ends of said legs attached to said proximal end of

said self-expanding stent, said legs extending proximally away from said self-expanding stent, each said leg including a flange adjacent its proximal end, said flanges are set within said grooves of said inner shaft, thereby releasably attaching said self-expanding stent to said inner shaft.

12. (Twice Amended) The apparatus according to claim 4 wherein said [removable member]stop is semi-cylindrical and snap fits over said inner shaft.

13. (Twice Amended) The apparatus according to claim 4 wherein said [removable member]stop has an outside diameter larger than an inside diameter of said outer sheath.